

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION**

**NOVARTIS AG, NOVARTIS
PHARMACEUTICALS CORPORATION,
MITSUBISHI TANABE PHARMA
CORPORATION, and MITSUI
SUGAR CO., LTD.**

PLAINTIFFS

CASE NO. 4:15-cv-95-KGB

EZRA VENTURES, LLC

DEFENDANT

**EZRA VENTURES, LLC'S OPPOSITION TO PLAINTIFFS' MOTION TO STAY THE
SECOND-FILED CASE IN THE EASTERN DISTRICT OF ARKANSAS**

I. INTRODUCTION

By their Motion, Plaintiffs seek to stay their own lawsuit that they filed nearly four months ago. Since the time Plaintiffs filed their Complaint, this Court entered a Proposed Scheduling Order setting this matter for trial in April of 2016, Ezra Ventures, LLC (“Ezra” or “Defendant”) answered and filed counterclaims, the parties conducted their Rule 26(f) conference, and Ezra issued written discovery. Despite all this activity and aggressive action by Plaintiffs in multiple jurisdictions, Plaintiffs now want to stay (but not dismiss) this lawsuit because Plaintiffs also filed an identical lawsuit in Delaware where jurisdiction is questionable. However, unlike the questionable jurisdiction in Delaware, all parties agree that the Eastern District of Arkansas is a proper forum in which to litigate this matter. It is also not disputed that the schedule set by this Court will result in resolution of this case approximately one year earlier than when the Delaware court will hold a trial. (Arkansas and Delaware Proposed Scheduling Orders, attached as Exhibits 1 and 2, respectively). Nevertheless, Plaintiffs Novartis AG, Novartis Pharmaceuticals Corp., Mitsubishi Tanabe Pharma Corp. and Mitsui Sugar Co., Ltd. (collectively “Plaintiffs”) instead seek to stay this action in favor of Case 1:15-cv-00150-LPS in the District of Delaware, where it is unresolved whether the court has jurisdiction over Ezra. Because expediency and judicial economy are best served by this Court retaining the case, and because neither party is substantially prejudiced by litigating in this Court, Ezra respectfully requests that this Court deny the motion to stay.

II. BACKGROUND

Ezra has filed an Abbreviated New Drug Application (ANDA) seeking permission to market its fingolimod product, which is a generic to Plaintiffs’ drug Gilenya®. As required by 21 U.S.C. § 355(j)(2)(B)(iii), Ezra sent a Paragraph IV Notice Letter to Plaintiff Novartis AG in

Switzerland, Novartis Pharmaceuticals Corp. in New Jersey, and to Mitsubishi Tanabe Pharma Corp. and Mitsui Sugar Co. Ltd. both in Japan (the “Notice Letter”). Plaintiffs filed suit in the District of Delaware against Ezra on February 11, 2015. (No. 1:15-cv-00150-LPS, D.I. 1.) (the “Delaware action”). Just two days later and long before any progress was made in Delaware, on February 13, 2015, Plaintiffs filed an identical suit in this Court. Both complaints alleged that the Ezra ANDA infringes US Patent 5,604,229 (the “229 patent”).

Because Ezra believes that it is not subject to personal jurisdiction in Delaware, Ezra filed a motion to dismiss the Delaware action on April 2, 2015. (Delaware action D.I. 13-14.). Before that, Ezra answered the Arkansas complaint on March 19, 2015. Prior to any meaningful progress in Delaware, this Court issued a scheduling order on April 10 setting the trial for the week of April 25, 2016. (Arkansas D.I. 23.)(Ex. 1). By oral order on May 11, 2015, the Delaware court denied Ezra’s motion without prejudice, allowing Ezra to raise the issue again pending the outcome of several pending Federal Circuit appeals involving “similar if not identical matters” to the personal jurisdiction issues Ezra raised in its motion. (Delaware action D.I. 27). Ezra moved for certification of the Delaware court’s decision for appeal to the Federal Circuit on May 21. (Delaware action D.I. 30-31, currently pending). On May 22, Plaintiffs filed the present motion. Ezra answered the Delaware complaint on May 27 as required by the deadline set by the Delaware court. The Plaintiffs have proposed a schedule in the Delaware action setting the trial for March of 2017, which is almost one year after this Court’s trial date. (Ex. 2). On June 1, Ezra served written discovery requests in the Arkansas case.

III. ARGUMENT

To obtain a stay, Plaintiffs “must make out a clear case of hardship or inequity in being required to go forward.” *Landis v. N. Am. Co.*, 299 U.S. 248, 255 (1936). In granting a stay, the

court “must weigh competing interests and maintain an even balance and must justify the stay by clear and convincing circumstances outweighing potential harm to the party against whom it is operative.” *Natl. Bank v. Panther Mt. Land Dev., LLC*, 686 F.3d 916, 926 (8th Cir. 2012).

Plaintiffs’ burden here is particularly high, given that this is a Hatch-Waxman action, for which Congress has legislated a delicate statutory timetable to “bring cheaper, generic copies of[] drugs to market.” *See Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 32 (D.D.C. 2000); *see also In re Brimonidine Patent Litig.*, MDL Docket No. 07-md-1866-GMS, 2008 WL 4809037 (D. Del. Nov. 3, 2008) (denying plaintiff pharmaceutical company’s motion to stay because the stay would most likely delay market entry of the generic product). As in other motions, Plaintiffs bear the burden of showing why their motion should be granted, and the facts should be taken in the light most favorable to the nonmoving party. *See, e.g., Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U. S. 574, 587 (1986)(in summary judgment context); *Hamm v. Goose*, 15 F.3d 110, 112 (8th Cir. 1994)(in Rule 12(b) motions). For the reasons set forth below, clear and convincing circumstances supporting the stay are not present here, and certainly are not sufficient to outweigh the harm of forcing Ezra, an Arkansas LLC with no direct contacts to Delaware, to litigate in Delaware, nor the harm to the public in delaying the resolution of this case by forcing the litigation to the longer Delaware schedule, which would consequently delay the potential introduction of Ezra’s less expensive generic product.

A. Jurisdiction in Delaware Remains Contested While Jurisdiction is Uncontested in This Court

In determining whether to stay a second-filed action, courts consider factors such as the “absence of jurisdiction over all necessary or desirable parties” in the first-filed action. *Elecs. for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1348 (Fed. Cir. 2005) (quotations omitted). Contrary to Plaintiffs’ contentions, jurisdiction in Delaware is not a settled issue. The Delaware court denied

Ezra's motion to dismiss without prejudice and with the understanding that it could present the motion again later precisely because personal jurisdiction is not a settled issue, particularly with respect to Hatch-Waxman cases. At least two such cases are pending at the Federal Circuit, with Ezra now having requested to join them with its appeal.

The Delaware court itself therefore acknowledged that personal jurisdiction over Ezra is not a closed issue. And for good reason: Ezra has only a single, indirect contact with Delaware and that contact (sending the Paragraph IV Notice Letter to Novartis in New Jersey, as Novartis is based in New Jersey but organized under Delaware law) is mandated by the Hatch-Waxman statute. The Supreme Court *Daimler* decision is recent and courts are still trying to determine the proper application of it to Hatch-Waxman cases. The Federal Circuit has yet to weigh in to provide such guidance post-*Daimler*.

Plaintiffs cite assorted cases for their position that jurisdiction is settled. Notably, the post-*Daimler* cases they cite all concern Mylan, a large generic drug manufacturer with hundreds of generic drugs sold across the U.S., which consequently is in a significantly different position with respect to jurisdictional matters than Ezra, which does not currently sell any products anywhere, much less in Delaware. Furthermore, Plaintiffs are incorrect that the jurisdictional dispute is not relevant. For example, in *Aventis Pharma Deutschland GmbH v. Lupin Ltd.*, 403 F. Supp. 2d 484, 491 (E.D. Va. 2005) the plaintiffs filed a first complaint against defendants in the District of Maryland and an identical so-called "protective" suit later in the Eastern District of Virginia. *Id.* at 488. Defendants consented to jurisdiction in the Eastern District of Virginia, but moved to dismiss the Maryland case for lack of personal jurisdiction. *Id.* at 488, 490. Like Plaintiffs here, the plaintiffs in *Aventis* relied on the first-to-file rule to justify a stay of the Virginia case. The Virginia district court denied the stay, giving great weight to the fact that

there was a pending jurisdictional dispute in the first-filed case. *Id.* at 490 (“If the Maryland forum is in any way questionable in order to necessitate a ‘protective filing’ as Plaintiffs maintain, then this Court is clearly the better forum, as all of the parties agree that both jurisdiction and venue lie here.”) (emphasis omitted); *see also Orthmann v. Apple River Campground, Inc.*, 765 F.2d 119, 121 (8th Cir. 1985) (dismissing first-filed case where personal jurisdiction was “vigorously dispute[d]”). Thus, where there remains a question of jurisdiction in the first-filed forum (as here), the second forum should exercise its discretion and deny a motion to stay. At the very least, Plaintiffs cannot discharge their clear and convincing burden on this argument.

Ezra expects that should its case be heard by the Federal Circuit, the denial of its motion to dismiss will be overturned. Even if Ezra’s case is not certified by the Federal Circuit, decisions in the other cases before that court will compel the reconsideration and granting of Ezra’s motion to dismiss. This determination would occur months in the future, possibly over a year into the future, and would result in substantial wasted effort in the Delaware court. This is particularly so when Arkansas is available and undisputed as a proper venue, and where Arkansas could conceivably (based on the respective schedules) finish the entire case before the jurisdictional issue in Delaware is finally resolved. It is undisputed that the Arkansas schedule is twice as fast as the Delaware schedule.

B. Equitable Considerations Favor This Court Exercising Discretion to Deny the Stay

The first-to-file “rule” is not absolute, but rather arises out of comity and convenience. It is “not intended to be rigid, mechanical, or inflexible, but should be applied in a manner serving sound judicial administration.” *Orthmann*, 765 F.2d at 121. Consequently, exceptions “are not rare, and are made when justice or expediency requires, as in any issue of choice of forum.”

Genentech, Inc. v. Eli Lilly and Co., 998 F.2d 931, 937 (Fed. Cir. 1993). Here, expediency and sound judicial administration counsel against a stay.

As discussed *supra*, given the respective scheduling orders, with a trial date some 11 months earlier here versus Delaware, it cannot be disputed that litigating in this venue will serve expediency. The trial in this Court will be completed at least a month before fact discovery closes in Delaware. The other parties in Delaware will greatly benefit from this Court's earlier views on claim construction issues. The Arkansas schedule will also require the parties to exchange their claim construction positions much earlier. These activities greatly increase the chances of a quicker resolution. Both Ezra and Plaintiffs, as well as the public¹ at large, have an interest in the fastest possible vindication of their respective rights. By litigating in this Court, even a Federal Circuit appeal of a decision here would likely be completed before a Delaware court would even reach a trial, providing the Delaware litigants and court with guidance on claim construction and other determinations on matters of law.

Importantly, any effort expended in this Court will not result in duplicative efforts. The discovery process will yield the same material regardless of venue; the only difference is that said process will occur much more quickly in Arkansas. The parties in Delaware have already agreed to avoid any duplicative or cumulative discovery that is common to this action. (See Ex. 2, ¶ 4). Likewise, other issues will be addressed more quickly in this Court. Plaintiffs can hardly claim to be prejudiced by obtaining a quicker resolution to the case.

Wishing to deny the public a generic version of Gilenya® as long as possible, it is both unfair and inefficient for Plaintiffs to first voluntarily file suit in Arkansas and then later seek to

¹ An earlier resolution in Ezra's favor would allow Ezra's cheaper generic product onto the market earlier, which would bring down costs for private insurance companies, and result in lower generic co-pays for patients.

stay the same lawsuit once Plaintiffs learn that the Arkansas court will decide the merits faster than the Delaware court. Furthermore, Plaintiffs' previous arguments to the Delaware Court that this Court is ill equipped to adjudicate this type of case are simply unfounded. See, Delaware Action, Plaintiff's Opposition to Motion to Dismiss, D.I. 20, pp. 17-18 ("Prior to Novartis's complaint, the Eastern District of Arkansas had never handled any Hatch-Waxman litigation, and has no patent rules. This [Delaware] Court, by contrast, has detailed and comprehensive local rules and a Default Standard for Discovery dealing precisely with patent litigation-specific issues.")

The cases cited by Plaintiffs where the two suits are filed by different parties² are of no import here, since Plaintiffs filed both actions. Plaintiffs chose to file the second action here because they knew that jurisdiction over Ezra in Delaware was questionable, and could well remain unsettled since two Delaware judges had certified personal jurisdictional issues for appeal to the Federal Circuit before Plaintiffs chose to file suit in Delaware. *Acorda Therapeutics, Inc. v. Mylan Pharms. Inc.*, Civ. Act. No. 1:14-cv-00935-LPS (D.I. 36.) and *AstraZeneca AB v. Mylan Pharms, Inc.*, Civ. Action No. 14-696-GMS, 14-664-GMS (D.I. 103.). Plaintiffs filed the second action because Arkansas was the only place where jurisdiction over Ezra was certain. Plaintiffs can hardly now be surprised that jurisdiction in Delaware is unsettled.

Plaintiffs cite cases where the second-filed Hatch-Waxman case was stayed. However, as discussed above, this is not immutable rule and at least one court has rejected such a stay for the exact situation presented here. See *Aventis*, 403 F. Supp. 2d 484 (discussed *supra*).

Determination of a stay must rest on the facts of each individual case. Where, as here, jurisdiction is only clear in the second-filed case, the second-filed case is further along than the

² These include *Brower v. Flint Ink. Corp.*, 865 F.Supp. 564 (N.D. Iowa 1994) and *Ray v. Am. Airlines, Inc.*, 2008 US Dist. LEXIS 42998 (W.D. Ark. 2008); Pl. Br. at 7-8.

first, the second-filed case will reach a conclusion nearly one year earlier than the first, and any appeal from the second-filed case will likely be complete before the first-filed even goes to trial, the equities weigh heavily against a stay. The prejudice to Plaintiffs in litigating to a faster conclusion in this Court is minimal. Since it is Plaintiffs that must show a clear and convincing case of hardship that outweighs the equities, the balance of prejudice against the equities compels a conclusion that the stay be rejected and litigation continue in this Court.

The present Arkansas action is readily distinguishable from many of the cases cited by Plaintiffs. Here, the second filed case is by the same Plaintiffs against the same defendant on the same legal theory. Plaintiffs cite to cases that involve a second filed case that is the declaratory judgment mirror image of the first filed case. These cases are inapplicable because the Plaintiff in the second filed case (as the Defendant in the first filed case) is filing a D.J. against the Defendant (as the Plaintiff in the first filed case). This Arkansas case is not a case where Ezra (as Defendant in the first filed case) is filing a D.J. in its home jurisdiction against Novartis et al. Also, many of the cases cited are in which the second filed D.J. case is significantly farther behind the schedule. Plaintiff cannot plausibly suggest that Delaware's two day head-start over Arkansas is meaningful considering zero significant activity occurred in that two day span.

Lastly, Plaintiffs contention at page 3, footnote 3 of Plaintiffs' brief is irrelevant. Here, it is not disputed that Arkansas is a valid forum. Indeed, it is possible that the trial in Arkansas and possible appeal to the Federal Circuit could be concluded in 30 months.

IV. **CONCLUSION**

For the reasons discussed above, Ezra respectfully requests Plaintiffs' motion be denied.

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CERTIFICATE OF SERVICE

I hereby certify that on June 5, 2015, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which shall send notification of such filing to the following:

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